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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/868,553	01/18/2002	Sing Hiem Yap	9250-37	1503

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EXAMINER

WANG, LOUISE Z

ART UNIT PAPER NUMBER

1648

DATE MAILED: 07/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/868,553

Applicant(s)

YAP ET AL.

Examiner

Louise Wang

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on June 18, 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,2,4-8 and 10-16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1,2,4-8 and 10-16 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date: \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

5.62

### **DETAILED ACTION**

Applicant's Preliminary Amendment, filed January 18, 2002, is acknowledged.

Claims 3 and 9 have been canceled.

Claims 1, 2, 4-8, and 10-14 have been amended.

Claims 15 and 16 have been added.

Claims 1, 2, 4-8, and 10-16 are pending.

It is noted that Claim 1 has a typographical error in line 5 between "non-A" and "G"; please replace the underscore with a hyphen.

It is also noted that Claim 12 is missing a space between "comprising" and "infecting".

Appropriate correction is required.

Additionally, the following is noted:

Claim 10 recites the limitation "hepatitis Y virus" which is not claimed in independent claim 5. There is insufficient antecedent basis for this limitation in the claim.

Claim 11 recites the limitation "antibody" which is not claimed in independent claim 6. There is insufficient antecedent basis for this limitation in the claim.

For restriction purposes, Claim 11 is presumed to depend on Claim 7 (an antibody). Clarification is required.

### ***Election/Restrictions***

Restriction is required under 35 U.S.C. 121 and 372.

Art Unit: 1648

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1, 11, and 15, drawn to a method for detecting a non-A-G hepatitis virus in a sample with an antibody.

Group II, claim 2, drawn to a human hepatocyte cell line.

Group III and IV, claims 4, 5, and 14, drawn to a nucleic acid vaccine comprising a nucleotide sequence.

Group IV, claims 6 and 13, drawn to a polypeptide vaccine.

Group V, claim 7, drawn to an antibody.

Group VI, claims 8, 10, and 16, drawn to a method for the detection of hepatitis Y virus with a nucleotide sequence.

Group VII, claim 10, drawn to a method for detecting hepatitis Y virus with a polypeptide.

Group VIII, claim 12, drawn to a method for growing Hepatitis Y virus.

The inventions listed as Groups I-VIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the common technical feature among these inventions is the method for detecting a non-A-G hepatitis virus in a sample. Such a method is disclosed in Shieh *et al.* (Mar, 1999) and Zhang *et al.* (Feb, 1998). Therefore, the technical feature is not a contribution over the art, thus, the claimed invention cannot be said to have unity of invention.

### ***Species Election***

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

For Groups IV, VI, and VIII above, Applicant is required to elect one of the following species: embodiments of the claimed inventions wherein the hybridization probe is:

- (a) a nucleic acid of the sequence of SEQ ID NO: 1
- (b) a nucleic acid of the sequence of the complement of SEQ ID NO: 1
- (c) a nucleic acid of the sequence of SEQ ID NO: 2
- (d) a nucleic acid of the sequence of the complement of SEQ ID NO: 2

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The following claims are generic: 6, 8, and 12.

### ***Conclusion***

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Art Unit: 1648

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***Contact Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louise Wang whose telephone number is 571-272-5543. The examiner can normally be reached on Mon-Fri, 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Louise Wang  
Patent Examiner  
June 21, 2005

  
**JEFFREY STUCKER**  
**PRIMARY EXAMINER**